Amendment No. 1 to HB1866

Lynn
Signature of Sponsor

AMEND Senate Bill No. 1935 House Bill No. 1866*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, is amended by adding the following as a new part:

56-7-3501. Legislative findings.

The general assembly finds and declares the following:

(1) Health insurance plans are increasingly making use of step therapy protocols under which patients are required to try one (1) or more prescription drugs before coverage is provided for a drug selected by the patient's healthcare provider;

(2) Step therapy protocols, where the protocols are based on well-developed, scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling healthcare costs;

(3) However, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug;

(4) Without uniform policies in this state for step therapy protocols, all patients may not receive the equivalent or most appropriate treatment;

(5) It is imperative that step therapy protocols in this state preserve the healthcare provider's right to make treatment decisions in the best interest of the patient; and

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(6) It is a matter of public interest that the general assembly require health insurers to base step therapy protocols on appropriate clinical practice guidelines or published peer reviewed data developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when those protocols are inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol when the patient's physician deems appropriate.

56-7-3502. Part definitions.

As used in this part:

(1) "Clinical practice guidelines" means a systematically developed statement to assist decision making by healthcare providers and patient decisions about appropriate health care for specific clinical circumstances and conditions;

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of healthcare services;

(3) "Emergency medical condition" has the same meaning as defined in § 56-7-2355;

(4) "Health plan" means a health benefit plan, as defined in § 56-61-102;

(5) "Insurer" means a health carrier, as defined in § 56-61-102;

(6) "Medically necessary" means healthcare services and supplies that, under the applicable standard of care, are appropriate:

(A) To improve or preserve health, life, or bodily function;

(B) To slow the deterioration of health, life, or bodily function; or

(C) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury;

(7) "Step therapy exception" means that a step therapy protocol is overridden in favor of immediate coverage of the healthcare provider's selected prescription drug;

(8) "Step therapy protocol" means a protocol, policy, or program that establishes a specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by an insurer or health plan; and

(9) "Utilization review organization" means an entity that conducts utilization review, other than an insurer or health plan performing utilization review for its own health plans.

56-7-3503. Clinical review criteria.

(a) Clinical review criteria used to establish a step therapy protocol must be based on clinical practice guidelines that:

(1) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(2) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(A) Requiring members to disclose any potential conflict of interest with an entity, including an insurer, a health plan, and a

pharmaceutical manufacturer, and recuse themselves from voting if the member has a conflict of interest;

(B) Using a methodologist to work with writing and review groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(C) Offering opportunities for public review and comment;

(3) Are based on high quality studies, research, and medical practice;

(4) Are created by an explicit and transparent process that:

(A) Minimizes biases and conflicts of interest;

(B) Explains the relationship between treatment options and outcomes;

(C) Rates the quality of the evidence supporting recommendations; and

(D) Considers relevant patient subgroups and preferences; and

(5) Are continually updated through a review of new evidence, research, and newly developed treatments.

(b) In the absence of clinical practice guidelines that meet the requirements of subsection (a), peer reviewed publications may be substituted.

(c) When establishing a step therapy protocol, a utilization review agent shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(d) This section does not require an insurer, a health plan, or this state to establish a new entity to develop clinical review criteria used for step therapy protocols.

56-7-3504. Exception process.

(a) If coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, or utilization review organization through the use of a step therapy protocol, then the patient and prescribing practitioner must

have access to a clear, readily accessible, and convenient process to request a step therapy exception. The process must be easily accessible on the website of the insurer, health plan, or utilization review organization. An insurer, health plan, or utilization review organization may use its existing medical exceptions process to satisfy the requirements of this subsection (a).

(b) An insurer, health plan, or utilization review organization shall grant a step therapy exception if:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient;

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) The patient, while under the current or a previous health insurance or health plan, has previously tried:

(A) The required prescription drug; or

(B) Another prescription drug in the same pharmacologic class or with the same mechanism of action as the required prescription drug, and the other prescription drug was discontinued due to a lack of efficacy or effectiveness, a diminished effect, or an adverse event;

(4) The required prescription drug is not in the best interest of the patient, based on medical necessity; or

(5) The patient is stable on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health insurance or health plan.

(c) Upon granting a step therapy exception, the insurer, health plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating healthcare provider.

(d) The insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within seventy-two (72) hours of receipt. However, if an emergency medical condition exists, then an insurer, health plan, or utilization review organization shall respond within twenty-four (24) hours of receipt. If a response by an insurer, health plan, or utilization review organization is not received within the time period required by this subsection (d), then the exception is granted.

(e) A step therapy exception is eligible for appeal by an insured.

(f) This section does not prevent:

(1) An insurer, health plan, or utilization review organization from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;

(2) An insurer, health plan, or utilization review organization from requiring a pharmacist to substitute a prescription drug consistent with the laws of this state; or

(3) A healthcare provider from prescribing a prescription drug that is determined to be medically appropriate.

56-7-3505. Rulemaking.

The commissioner of commerce and insurance shall promulgate rules to effectuate this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

56-7-3506. Applicability.

This part applies to any group health plan or health insurance coverage offered in connection with a group health plan that provides coverage for a prescription drug pursuant to a policy that meets the definition of a medication step therapy protocol as defined in § 56-7-3502, regardless of whether the policy is described as a step therapy protocol, and includes any state or local insurance program, under title 8, chapter 27,

and any managed care organization contracting with the state to provide insurance through the TennCare program.

SECTION 2. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. For the purpose of promulgating rules, this act shall take effect upon becoming law, the public welfare requiring it. For all other purposes, this act shall take effect January 1, 2021, the public welfare requiring it, and applies to agreements for health insurance or health plans entered into, amended, or renewed on or after that date.